



JPW 1646

PATENT  
ATTORNEY DOCKET NO.: STEM1110-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Twardzik et al.  
Application No.: 09/932,172  
Filed: August 17, 2001  
Title: TGF- $\alpha$  POLYPEPTIDES, FUNCTIONAL FRAGMENTS AND METHODS OF USE THEREFOR

Art Unit: 1646  
Examiner: To Be Assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL SHEET

Sir:

Transmitted herewith for the above-identified application, please find:

1. Information Disclosure Statement (2 pages);
2. Form PTO-1449 (3 pages);
3. Nineteen References;
4. Supplementary European Search Report (12 pages); and
5. Return postcard.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on May 13, 2004, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Karen LePari*

Karen LePari

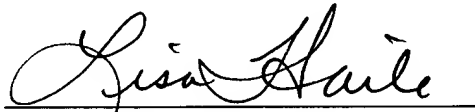
In the Application of:  
Twardzik et al.  
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Page 2

PATENT  
Attorney Docket No. STEM1110-3

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement as the items of information contained in this statement were cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated February 13, 2004, which is not more than three months prior to the filing of this statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: May 13, 2004



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**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. References cited in a previously filed Information Disclosure Statement on October 18, 2002, in this matter, are not included. For the convenience of the Examiner, the remaining references are listed on the attached Form PTO-1449 and copies are enclosed.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on May 13, 2004, in an envelope addressed to:  
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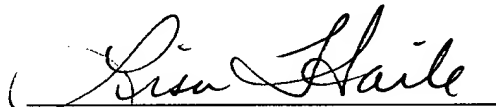
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<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office	<b>Docket No.</b> STEM1110-3	<b>Serial No.:</b> 09/932,172
	<b>Applicants:</b> Twardzik et al.	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>Filing Date:</b> August 17, 2001	<b>Group Art Unit:</b> 1646

### U.S. PATENT DOCUMENTS

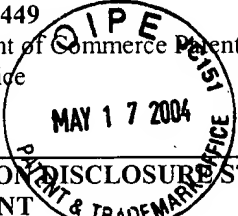
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	DP	4,863,902	09/05/1989	Harunobu Amagase et al.			
	DQ	5,240,912	08/31/1993	George J. Todaro			
	DR	5,814,308	09/29/1998	Ke Zhang			
	DS	5,942,487	08/24/1999	Takahiro Ogawa et al.			
	DT	6,486,122 B1	11/26/2002	Daniel R. Twardzik et al.			

### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	DU	WO 95/19785	07/27/1995	PCT			
	DV	WO 98/19712	05/14/1998	PCT			
	DW	WO 99/56785	11/11/1999	PCT			
	DX	WO 00/65028	11/02/2000	PCT			
	DY	WO 03/016480 A2	02/27/03	PCT			

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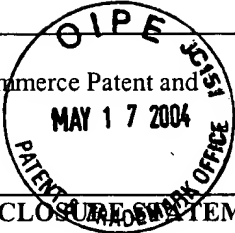
<b>FORM PTG-1449</b> U.S. Department of Commerce Patent and Trademark Office 	<b>Docket No.</b> STEM1110-3	<b>Serial No.:</b> 09/932,172
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	<b>Filing Date:</b> August 17, 2001	<b>Group Art Unit:</b> 1646

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)**

	DZ	Cashman, Johanne D. et al, "Mechanisms That Regulate the Cell Cycle Status of Very Primitive Hematopoietic Cells in Long-Term Human Marrow Cultures. I. Stimulatory Role of a Variety of Mesenchymal Cell Activators and Inhibitory Role of TGF- $\beta$ ", <i>Blood</i> , Vol. 75, No. 1, pp. 96-101, 1990.
	EA	Gandrillon, Olivier et al., "TFG- $\beta$ cooperates with TFG- $\alpha$ to induce the self-renewal of normal erythrocytic progenitors: evidence for an autocrine mechanism", <i>European Molecular Biology Organization</i> , Vol. 18, No. 10, pp. 2764-2781, 1999.
	EB	Hayman, Michael J. et al., "Self-Renewal and Differentiation of Normal Avian Erythroid Progenitor Cells: Regulatory Roles of the TGF $\alpha$ /c-ErbB and SCF/c-Kit Receptors", <i>Cell</i> , Vol. 74, pp. 157-169, 1993.
	EC	Huang, Frederick S. et al., "Role of epidermal growth factor and its receptor in chemotherapy-induced intestinal injury", <i>Am. J. Physiol. Gastrointest Liver Physiol</i> , Vol. 282, pp. G432-G442, 2002.
	ED	Justicia, Carles and Planas, Anna M., "Transforming Growth Factor- $\alpha$ Acting at the Epidermal Growth Factor Receptor Reduces Infarct Volume After Permanent Middle Cerebral Artery Occlusion in Rats", <i>Journal of Cerebral Blood Flow and Metabolism</i> , Vol. 19, pp. 128-132, 1999.
	EE	Rudinger, J., "Characteristics of the amino acids as components of a peptide hormone sequence", Biological Council, The Co-ordinating Committee for Symposia on Drug Action, pp. 1-7, 1976 (out of print).
	EF	Sharp, Richard et al., "Transforming growth factor $\alpha$ disrupts the normal program of cellular differentiation in the gastric mucosa of transgenic mice", <i>Development</i> , Vol. 121, pp. 149-161, 1995.
	EG	Walz, Thomas M., "Transforming Growth Factor- $\alpha$ (TFG- $\alpha$ ) in Human Bone Marrow: Demonstration of TFG- $\alpha$ in Erythroblasts and Eosinophilic Precursor Cells and of Epidermal Growth Factor Receptors in Blastlike Cells of Myelomonocytic Origin", <i>Blood</i> , Vol. 85, No. 9, pp. 2385-2392, 1995.

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	EH	Yamashita, Hiroshi and Oesterle, Elizabeth, "Induction of cell proliferation in mammalian inner-ear sensory epithelia by transforming growth factor $\alpha$ and epidermal growth factor", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pp. 3152—3155, 1995.
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